NDA 20-429/S-004

Whitehall-Robins Healthcare AUG 2 3 2000
Attention: Sharon Heddish
Vice President, Regulatory Affairs - Worldwide
Five Giralda Farms
Madison, NJ 07940-087 1 Dear Ms. Heddish:

Please refer to your supplemental new drug application dated January 14,2000, received January 18, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Orudis KT (ketoprofen) Tablets and Caplets, 12.5 mg.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to implement the allergy alert statements required by our September 15, 1998 letter, and the alcohol warning required by the final rule published on October 23, 1998 (63 FR 56789).

We have completed the review of this supplemental new drug application and have concluded that adequate infonnation has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted on January 14,2000. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

We request that the following revisions in the labeling for this drug product be implemented within 180 days or at the next printing, whichever comes first:

1. In the Allergy Alert statement, the letter "k" in "ketoprofen" should be in upper case.

2. The subheader, "Stop using this product and ask a doctor if' should read "Stop use and ask a doctor if' consistent with the September 15, 1998 letter and 21 CFR 201.66. Under this header, a period should be placed at the end of the second sentence in the first bulleted statement.

3. The pregnancy/breast-feeding statement and the accidental overdose warning need to be revised to read as follows:

   "If pregnant or breast feeding, ask a health professional before use. It is especially important not to use ketoprofen during the first 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

   Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away."

4. Under the Uses section, the phrase "common cold" should be revised to read "the Common cold" and the letter "t" in the word "Temporarily" should be in lower case.

5. The storage information for the 24,50, and 100-count bottles and cartons should be revised so that the letters "s" in "Store" and "a" in "Avoid" respectively should be in lower case. In addition, the period following the "store at..." statement should be removed.

6. On the immediate container, the alcohol warning should follow directly after the allergy alert warning. Also, the lot number, expiration date, and the first bulleted statement under the "Stop using this product and ask a doctor if," section should appear on the labeling.

Furthermore, we note that the labeling was not submitted in Drug Facts format consistent with the requirements of the March 17, 1999 FEDERAL REGISTER document "Over-the-Counter Human Drugs; Labeling Requirements; Final Rule" (64 FR 13254) (OTC labeling final rule), which has been incorporated into the regulations at 21 CFR 201.66. We remind you that the labeling of your product must be revised to reflect the Drug Facts format within the timeframes specified in the OTC labeling final rule.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this application, please contact Thomas Parmelee, Pharm.D., Regulatory Project Manager, at 301-827-2271.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research